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No. 08-624

IN THE
Supreme Court of the United States

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S,

Petitioners,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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REPLY BRIEF FOR THE PETITIONER

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Any cognizable dispute underlying this case is dead. Plaintiff Caraco brought suit alleging a controversy over whether it infringed Forest's '941 patent. Forest then gave Caraco a covenant not to sue on that patent. That should have been the end of the matter. Article III justiciability does not exist where the underlying congressionally defined cause of action regarding infringement is unsustainable.

The Federal Circuit reached a different result only by reformulating the limited cause of action Congress actually created (one to resolve infringement disputes) into a new cause of action that Congress did not see fit to create (one to resolve disputes with Orange Book listing). Since Orange Book listing is mandatory under pain of criminal sanction (an uncontested point), the decision below is not only an affront to Article III, but an assault on core separation of powers principles defended by Article III. *Allen v. Wright*, 468 U.S. 737, 752 (1984). Only Congress can rewrite Hatch-Waxman.

Not only the legal stakes, but the economic and public health stakes of this case are enormous. None of the reasons Caraco offers to avoid review survives scrutiny. Indeed, Caraco never pointedly denies the immense significance of this case for preserving the balance of incentives for new drug innovation as against generic competition. The issues involved and the attestations of *amici* readily demonstrate that this case is one of exceptional importance.

Moreover, most cases involving Hatch-Waxman disputes cannot create circuit splits because of the Federal Circuit's exclusive jurisdiction over patent matters. Hence, it is a testament to the magnitude of the errors committed below that this Hatch-Waxman case fuels a number of more general splits

concerning Article III. Caraco's 34-page opposition launches mostly merits-based defenses, which, while rebutted below, are better tested in subsequent merits briefing.[1]

* * * *

Caraco argues that Forest cannot obtain *certiorari* because Forest conceded (i) CAPC actions reach to full constitutional limits; and (ii) Forest's listing of the '941 patent in the Orange Book is a "but for" cause of alleged injury. Opp. 12. The first purported concession establishes nothing, and the second was never conceded. Actions under the Declaratory Judgment Act are similarly coextensive with Article III's limits. *See* 28 U.S.C. § 2201(a) ("actual controversy"). The question here is whether the grant of a covenant not to sue takes this case beyond Article III. In terms of the causation element of standing, Forest plainly contended that Orange Book listing cannot be a basis for asserting injury against Forest because listing is mandated by Congress. Pet. 6-7, 25-31.

Caraco asserts that because Forest's arguments require consulting the text of Hatch-Waxman, they are "statutory arguments," and hence fall outside the Article III questions presented. Opp. 12-13, 15, 18.

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[1] In one of its rare, non-merits points, Caraco calls this petition interlocutory. Opp. 1. But cases where review is urged regarding rulings on motions to dismiss fall into a category of cases the Court frequently accepts. For instance, in *Allen*, the Court reviewed the D.C. Circuit's reversal of a dismissal on standing grounds. *See also* Eugene Gressman, et al., SUPREME COURT PRACTICE, § 4.18, at 281-82 (9th ed. 2008) (collecting other such cases).

But even if the Federal Circuit's statutory misconstructions were not fairly encompassed within Forest's questions (which they are), no rule holds that constitutional standing questions must be evaluated without resort to statutory construction concerning the cause of action at issue. *International Primate Protection League v. Administrators of Tulane Educ. Fund*, 500 U.S. 72, 77 (1991).

A. Caraco's Arguments Defending Actionable Injury in Fact

1. Forest never contended that the civil action to obtain patent certainty ("CAPC") authorized only first ANDA filers to bring declaratory actions against patentees. Caraco's suggestion that Forest's petition rests on such a contention (Opp. 1-2, 13, 15) is a straw man and provides no basis for sustaining the decision below. The simple fact is that the Federal Circuit took a cause of action designed to resolve validity and infringement disputes and contorted it into a cause of action premised on injury from Orange Book listing decisions. App. 26a-27a.

The terms Caraco uses in defining CAPC actions are themselves revealing. According to Caraco, the cause of action is not one to resolve infringement disputes, but one designed to vindicate its supposed "*right to a ruling* on whether its product infringes valid Orange Book-listed patents." Opp. 16 (emphasis added). Countenancing freestanding "rights to rulings" (though not what Congress created here) would eviscerate Article III.

2. From there, Caraco argues that Forest merely assumes that CAPC suits can do no more than resolve infringement disputes. Opp. 14-16. This

argument fails under the plain text: "[T]he applicant . . . may . . . bring a civil action . . . against the owner or holder . . . for a declaratory judgment that the patent is invalid or will be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II). Orange Book listing injuries are not made actionable.

3. Caraco heavily flavors its opposition with claims that Forest is "gaming" Hatch-Waxman. Opp. 19. The claims are unsupportable. Forest took only two actions that the Federal Circuit or Caraco have pointed to as potentially causing Caraco's alleged injury: (i) listing the '941 patent in the Orange Book, and (ii) granting Caraco a covenant not to sue. Neither represents gaming. To reiterate, Orange Book listing is mandatory, and failure to list can result in criminal penalties. Pet. 6-7, 29. Complying with a government mandate cannot possibly be labeled as gaming. Nor can granting a covenant not to sue. As the Federal Circuit conceded, "[i]f a threat of suit was the only action allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case." App. 34a. In other words, granting the covenant was not "gaming," but legitimate action foreseeably leading to mootness.

4. The Federal Circuit's expansion of the rights of laggard ANDA filers would also make structural hash of the four-paragraph set of Hatch-Waxman certification options. As Caraco recognizes, beyond the paragraph IV certifications of Ivax and Caraco at issue here, ANDA filers can make paragraph I certifications. Opp. 3 (paragraph I, in Caraco's own words, is "a statement that *the required information* relating to the patent has not been filed with the

FDA") (emphasis added). Therefore, the very concept of a paragraph I certification would make no sense if Orange Book listing were not mandatory. *Astoria Fed. Sav. & Loan Ass'n. v. Solimino*, 501 U.S. 104, 112 (1991) ("we construe statutes, where possible, so as to avoid rendering superfluous any parts thereof").

5. Caraco tries to take back what the Federal Circuit conceded (without Orange Book listing, Forest's covenant would have mooted this case) by arguing that Forest was somehow obligated not just to promise not to sue, but to go further and concede noninfringement. Opp. 17-19 & n.4. This is against all reason. Cases can be settled and thus mooted (and frequently are) without one side entirely capitulating to the demands of its opponent. Nothing in Hatch-Waxman requires Forest to enter into a stipulation or consent decree finding noninfringement.

6. Relying on Senator Kennedy standing alone, Caraco argues that Congress was troubled by covenants not to sue when it amended Hatch-Waxman in 2003 through the "MMA." Opp. 5-6. That effort falters because Congress could have regulated or restricted such covenants, but did not (despite making other adjustments to exclusivity rights for first filers). Indeed, Caraco ignores the Federal Circuit's attempt to bury Senator Kennedy's caveat that, for Article III reasons, the new CAPC action may not operate against such covenants. Pet. 13-14. Judge Friedman highlighted this caveat. App. 42a.

7. Despite paying lip service to the balance struck in Hatch-Waxman between incentivizing innovation and price reduction, Opp. 2, Caraco seeks

to prop up the Federal Circuit's rebalancing of those statutory policies, which failed to honor the three distinct phases created by the statute:

Phase I:	A period of monopoly for the pioneer.
Phase II:	A duopoly period where the pioneer and the first ANDA filer share exclusivity.
Phase III:	A period where the pioneer and all ANDA filers compete on equal footing.

CAPC actions are the gateway between Phases I and II to Phase III. But there is no statutory indication that the economic returns Forest obtains under Phases I and II may be cut short by ignoring the limits of CAPC actions as set against Article III. As is clear from Caraco's five citations (Opp. 4, 5, 6, 8) to Judge Gajarsa's (not Judge Dyk's) dissent from denial of rehearing *en banc* in *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 405 F.3d 990 (Fed. Cir. 2005), what the Judges sympathetic to Caraco rely on to establish standing are not actions by the pioneer, but policy fears for laggard generics given "th[e] bottleneck under the statute." *Id.* at 994 (Gajarsa, J., dissenting). That, however, is a disagreement with Congress.

8. Caraco then turns for support to *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), Opp. 19-20, where the D.C. Circuit suggested that later ANDA filers sometimes "buil[d] a better mousetrap." *Id.* at 1073. But *Mova* was issued *before* the MMA amended Hatch-Waxman. In the MMA, Congress itself carefully balanced the incentives it wanted to create for pioneers, first ANDA filers, and later ANDA filers. Pre-MMA

musings in D.C. Circuit *dicta* are unavailing.

9. In an attempt to turn the MMA's advent to its side, Caraco argues that this case is a "relic." Opp. 14, 20-21. Untrue. The Federal Circuit majority was quite clear that its holding will apply equally to the pre- and post-MMA regimes. App. 10a n.4 ("under *both* . . . *provisions*, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed") (emphasis added). *See also* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (post-MMA judgment trigger serving same basic function as pre-MMA judgment trigger in 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000)); WLF Br. 12, 22 & n.10.

10. Forest argues that the circuits are in conflict over whether a "legally protected right" is a precondition to demonstrating injury-in-fact. Pet. 17-25. Caraco provides no response, except to assert that *MedImmune* controls. Opp. 22-23. But that case does not even involve Hatch-Waxman.

Caraco argues that because *MedImmune* found standing regarding a licensing dispute, and because a patent license is an "enforceable covenant not to sue," Opp. 22-23, *MedImmune* controls. But even the Federal Circuit panel did not make that claim. The panel maintained only that *MedImmune* required testing for case or controversy under the totality of circumstances. App. 22a.

MedImmune is perfectly consistent with this petition. All *MedImmune* holds is that a licensee can make licensing payments under protest without surrendering its ability to challenge the license's applicability in the first place. As section II of

MedImmune crystallizes, the licensee had a valid cause of action under a common law contract theory. 549 U.S. at 123-25. Here, there is no contract between Caraco and Forest. Caraco's only cause of action is a statutory one concerning whether it infringed the '941 patent. Justiciability was not destroyed by the license in *MedImmune*, *compare* Opp. 23, because that dispute centered on the license's applicability. Here, the terms and effect of the covenant are not in dispute.[2]

11. Caraco also tries to evade the point that the Federal Circuit's covenant-not-to-sue cases are confused by arguing that all such cases predate *MedImmune*. Opp. 24. But the Federal Circuit's decision in *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007) (allowing covenant to create mootness), post-dates *MedImmune*. Indeed, the *Benitec* panel called for supplemental briefing on *MedImmune*. Moreover, Judge Dyk's dissent deplored the confusion. *See id.* at 1354 ("The majority's decision here is not only inconsistent with the Supreme Court precedent; it exposes an inconsistency in this court's own jurisprudence.").

12. Finally, Caraco attempts to duck the confusion engendered by *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008) (holding covenant mooted CAPC dispute). Opp. 25-26. Winston & Strawn (Caraco's counsel here),

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[2] *MedImmune* also makes clear that its outcome may have been different if there had been a separate waiver of the licensee's ability to seek contract relief. 549 U.S. at 125. Hence, Forest's waiver of its *only* right—to sue for infringement—also sets this case apart from *MedImmune*.

however, has elsewhere acknowledged that it reads *Janssen* to mean that "*possible future delay by a first Paragraph IV ANDA filer* in launching its generic product does not harm a second Paragraph IV ANDA filer sufficiently to create a case or controversy."[3]

This raises the issue of ripeness—the heart of Judge Friedman's dissent.[4] On that score, Caraco does not contest *amicus* WLF's observation that the most likely outcome here is that, even if the decision below is allowed to stand, the earliest Caraco could enter the market for Lexapro® is *180 days after* the expiration of the '712 patent *in 2012*. WLF Br. 20.

B. Caraco's Arguments Defending Causation

1. Caraco argues that Forest only had to list the '941 patent if it wanted to claim Hatch-Waxman's exclusive-marketing benefits. Opp. 13, 27. This ignores: (i) Caraco's failure to answer Forest's point that the failure to list can bring criminal sanctions, Pet. 29; and (ii) Caraco's failure to counter Ivax's point that bad faith listing decisions can bring antitrust liability, Ivax Br. 20-21.

2. Caraco also seizes on the word "ministerial" to describe the listing obligation, as if that term meant an insubstantial obligation that cannot constitute an intervening cause of Caraco's alleged injury. Opp. 3,

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[3] Patent Decision Summaries, http://www.winston.com/siteFiles/publications/FedCircSumVol1,Issue19.html (emphasis added).

[4] Caraco attempts to neutralize Judge Friedman's dissent by listing points Judge Friedman did not speak to, as if that means he agreed with Caraco. Opp. 11-12.

28 (accusing Forest of mischaracterizing Hatch-Waxman). But as a matter of basic administrative law, the term "ministerial" reinforces, rather than undermines, the need for Orange Book listing. *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (ministerial duties are "non-discretionary act[s]"). Cases holding that the listing obligation is ministerial mean the FDA has no choice but to list patents identified by innovators. *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001). Neither do such innovators have any listing discretion.[5]

3. Although it failed to challenge the existence of the circuit split Forest identified to support its first question presented, Pet. 17-19 & nn. 8-9, Caraco does attempt to rebut the existence of a relevant circuit split on the second question. Opp. 29-30. Beginning with *Bronson v. Swensen*, 500 F.3d 1099 (10th Cir. 2007), Caraco says that case is inapposite because the actions of the county clerk had not yet caused any injury, whereas Forest's listing decision has already caused injury. Opp. 29. In reality, however, Forest's Orange Book listing has also not yet caused Caraco any injury. This was a lynchpin of Judge Friedman's dissent. App. 40a.

4. Caraco argues that *Fulani v. Brady*, 935 F.2d 1324 (D.C. Cir. 1991), is inapplicable because it rested on special standing rules in tax cases. Opp. 29. The analysis in *Fulani* to which Forest pointed,

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[5] Caraco argues that *Alphapharm Pty. Ltd v. Thompson*, 330 F. Supp. 2d 1 (D.D.C. 2004), found Forest to have improperly listed a patent. Opp. 28 n.6. That *non sequitur* was never tested on the merits and Forest denies it.

however, is not unique to tax cases. *See id.* at 1328-31. Moreover, there is no standing rule that cordons tax cases off as untouchable precedent in non-tax cases. *See, e.g.*, *Sprint Commc'ns. Co. v. APCC Servs., Inc.*, 128 S. Ct. 2531, 2535 (2008) (non-tax standing case citing tax standing case of *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332 (2006)).[6]

5. Caraco is also incorrect that Forest is simply challenging the *application* of *Duke Power Co. v. Carolina Envt'l Study Group, Inc.*, 438 U.S. 59, 74 (1978). Caraco proceeds as if *Duke Power* embodies all Supreme Court standing jurisprudence. Caraco ignores the discussion of how the decision below conflicts with *Lujan*, *Allen*, *Simon*, and *Warth*. Pet. 27-28.

6. Caraco claims that it is not circumventing Ivax's 180-day exclusivity because overcoming that period is merely the fringe benefit of Caraco exercising its right to challenge Forest's Orange Book listing. Opp. 31. This argument falters on the same point as Caraco's entire case—there is no such Orange Book cause of action. *Supra* 3.

7. Finally, Caraco claims on the merits that Forest's causation analysis runs afoul of *Bennett v. Spear*, 520 U.S. 154 (1997). Not so. In *Bennett*, holders of water rights challenged a Fish and Wildlife Service ("FWS") determination effectively

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[6] Caraco suggests that a split between the D.C. Circuit's *Fulani* decision and another case involving candidate Fulani in the Second Circuit is "stale." Opp. 32. This ignores that Forest posited a split between the decision below and *Fulani plus Bronson*, and never mentioned the Second Circuit case.

redirecting privately owned water to endangered suckerfish. The government protested that the Bureau of Reclamation (also part of the Interior Department) *might* choose not to follow the FWS determination, thereby interrupting causation. This Court rejected that defense, noting that there was no "*independent*" break in the causal chain, *id.* at 169, especially where the FWS determination had "virtually determinative effect," *id.* at 170, and was thus the predominant cause of the private injuries. Here, the actions of Congress in mandating Orange Book listing are neither attributable to Forest, nor those of a mere sister sub-agency.[7]

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[7] Caraco also cites *Khodara Environmental, Inc. v. Blakey*, 376 F.3d 187, 195 (3d Cir. 2004) (Alito, J.). *Khodara* holds that there can be multiple actionable causes of an alleged injury, but only where "there are multiple sufficient causes." Here, as the Federal Circuit admitted, there is but one supposedly sufficient cause—Orange Book listing.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for writ of certiorari.

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